UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler
	)	**Leave to file granted: 9/11/2007**

ABBOTT LABORATORIES, INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS OR PARTIALLY DISMISS THE UNITED STATES' FIRST AMENDED COMPLAINT

Dated: September 17, 2007

James R. Daly
Tina M. Tabacchi
Jason G. Winchester
Brian J. Murray
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601
Telephone: (312) 782-3939
Facsimile: (312) 782-8585

R. Christopher Cook
David S. Torborg
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
Telephone: (202) 879-3939
Facsimile: (202) 626-1700

Counsel for Defendant Abbott Laboratories, Inc.

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MISCELLANEOUS

INTRODUCTION

The Government's opposition ("Opp.") and the Relator's opposition ("Relator Opp.") confirm that nearly all (or, in the alternative, certain categories) of the United States' claims against Abbott should be dismissed, based on the three grounds briefed in Abbott's Motion to Dismiss or Partially Dismiss the United States' First Amended Complaint (Dkt. No. 4470):

- Claims relating Acyclovir Sodium must be dismissed: the Government did not seek leave to add them; leave would have been improper in any event; there are no claims as to this drug left to add; and in any event, the Government has not demonstrated the required "good cause" to add them now. (*Id.* at 6-13.)

- Under the Second Circuit's decision in *United States v. Baylor University Medical Center*, 469 F.3d 263 (2d Cir. 2006), any claims preceding March 17, 2000—six years prior to the March 17, 2006 filing of the United States' Complaint—are untimely and must be dismissed. (*Id.* at 13-18.)

- At the very least, claims relating to any particular NDC or J-Code should relate back only to the complaint in which a particular NDC or J-Code was first named by Ven-A-Care. (*Id.* at 18-20.)

This reply focuses on the first and third of these grounds.[1]

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[1] Abbott stands on its Motion to Dismiss arguments regarding Rule 15(c) relation back of the FCA claims, which, unlike the *Dey* motion, is supported by facts demonstrating prejudice from the Government's delay. (Dkt. No. 4470 at 15-18); *see In re Pharm. Indus. Average Wholesale Price Litig.*, _ F. Supp. 2d _, 2007 WL 2058731 at *7 (D. Mass. July 17, 2007) (finding relation back to relator's under-seal complaint under Rule 15(c)(1) proper, despite decade-plus delay in unsealing complaint, because "Dey has not produced any evidence that these extensions were . . . prejudicial"). This reply also does not deal with the Government's "response" to two issues that Abbott never raised in its motion to dismiss, issues which this Court should likewise ignore.

First, the Government asks the Court to reconsider its ruling from the *Dey* case that the Government's common-law claims do not relate back. (Opp. at 9.) Abbott did not raise the issue of the relation back of common law claims in its Motion to Dismiss, and the United States' opposition is out of place and improper here. If the Government would like the Court to reconsider that ruling in the *Dey* litigation, it should have filed a motion for reconsideration in that case. *McLaughlin v. Unum Life Ins. Co.*, 212 F.R.D. 40, 41 (D. Me. 2002) (setting out standards for motion for reconsideration).

Second, the United States' First Amended Complaint included a number of new paragraphs the Government contends seek to "add claims" relating to Abbott's home infusion business. (Opp. at 5.) Citing no allegedly unfulfilled document requests to Abbott, the Government claims it is justified in adding allegations relating to Abbott's home infusion business because "Abbott never provided information regarding this business to the United States prior to the filing of the United States' original Complaint." (*Id.* at 5.) The Government's motion does not even try to support its hyperbolic assertions of concealed evidence. They provide no justification for leave to amend to add these allegations.

Moreover, it is not clear if the United States' allegations relating to Abbott's home infusion business seek recovery on additional "false claims," as opposed to adding facts to support existing claims. If the Government is seeking recovery on new false claims submissions not identified in the Relator's prior complaints, statute of

ARGUMENT

I. THE GOVERNMENT MAY NOT AMEND ITS COMPLAINT TO ADD ACYCLOVIR CLAIMS.

The Government never sought leave to file its second amended complaint, which by itself is reason enough to dismiss it. Even if the Court were willing to overlook that, though, the Government's new claims are triply barred: (1) there is no justification for granting leave to add them now under the Federal Rules of Civil Procedure; (2) even if there were such a justification, there are no Acyclovir claims for the Government to intervene in because they were dropped from the underlying Ven-A-Care case months ago; and (3) even if these two hurdles could be overcome, the Government must also demonstrate "good cause" under the False Claims Act ("FCA") to add these claims now—and it has not remotely approached such a showing.

A. The United States' Sole Justification For Adding Acyclovir Claims—"Newly Obtained Evidence"—Is Demonstrably False.

The Government contends that leave to add new claims based on Acyclovir should be granted, and is "justified in light of . . . newly obtained evidence." (Opp. at 2.) The Government asserts that, "[s]ince the filing of the original Complaint, the United States has obtained additional evidence regarding Abbott's drug pricing conduct," including "new evidence" that allegedly shows "actionable fraudulent conduct involving the marketing of a megaspread Abbott drug, Acyclovir Sodium." (*Id.* at 1-2) The Government relies on only two pieces of allegedly "new evidence": (1) five pages of April 8, 2007 testimony from Abbott employee Dennis Walker, and (2) an exhibit referred to in that deposition. (*Id.* at 7.) Both the testimony and exhibit relate to conduct that allegedly occurred in 1997. Yet, the Government now claims that

(continued…)

limitations issues would arise and would need to be briefed separately. In any event, because the Government did not seek leave to file its *second* amended complaint (*see* Dkt. No. 4470 at 9-10; *infra* at I.D), the Government's allegations have "no legal effect." *Ritzer v. Gerovicap Pharm. Corp.*, 162 F.R.D. 642, 644 (D. Nev. 1995).

this evidence is "new" and "prompted the United States to add the drug to its First Amended Complaint." (*Id.*)

The Government's claim of "newly discovered evidence" is false, and the Government knows it. As discussed below, Mark Lavine, one of the Department of Justice ("DOJ") attorneys who signed the response brief making these assertions, was personally aware of this "evidence" literally *hours* after the event in question transpired—over *ten years ago*.

The Government's "new evidence" of "marketing the spread" for Acyclovir is, in fact, the same alleged conversation and fax transmission that Ven-A-Care specifically identified and attached to its August 13, 1997 Second Amended Complaint. (*See* Ex. A at 25-27.) In that complaint, Ven-A-Care claimed that Abbott employee Dennis Walker called Ven-A-Care's Zachary Bentley on May 30, 1997, in response to a call he received from Mr. Bentley. According to Ven-A-Care, Walker told Bentley that "Abbott was committed to capturing market share by 'widening the spread for providers.'" (*See id.* at 26.) Importantly, Ven-A-Care attached a copy of a one-page fax transmission dated the same day (May 30, 1997) from Mr. Walker to Mr. Bentley as Exhibit 2 to its Second Amended Complaint. (*See* Ex. A.) In this fax, sent two years after Abbott was named in Ven-A-Care's original complaint, Mr. Walker simply provided the price and AWP information for Acyclovir that *Mr. Bentley* had requested. (*See id.*)[2] Interestingly, the DOJ withheld this documentary evidence of the Government's false assertion of "newly discovered evidence" in this case. The Government was ordered, by the Southern District of Florida, to provide Abbott with "[c]opies of the Relator's prior complaints redacted to disclose only that information pertinent to the allegations against Abbott." (Ex. B.) The

[2] That Mr. Bentley was fishing for information to support Ven-A-Care's complaint in this case, which had already been filed some two years prior and was still under seal, is clear enough. Whether he did so at the behest of the Government is less clear—though he was quick to report his activities to the Government lawyers running this case, as set out below.

Government, however, did not provide copies of the Ven-A-Care/Walker exhibit to the Second Amended Complaint, even though that exhibit related only to Abbott, when it provided redacted copies of the complaints to Abbott in May of 2006. Abbott may not even have known about the Government's concealment had it not received those exhibits in connection with the State of Texas's litigation against Abbott, where Ven-A-Care is also the Relator.

The Government may claim that the "newly discovered evidence" is actually the April 8, 2007 testimony of Mr. Walker. In fact, that testimony adds nothing at all to the facts known to the Government in 1997. (*See* Ex. C at 285:9-290:21.) The DOJ's contention that it does is false. During this April 8, 2007 testimony, Mr. Walker was asked about the May 30, 1997 fax he sent to Mr. Bentley that was attached as Exhibit 2 to Ven-A-Care's Second Amended Complaint. Mr. Walker provided no "new evidence" about alleged marketing of the spread for Acyclovir. He simply recalled sending the May 30, 1997 fax, and testified about the literal contents of the document. (*See id.*) Indeed, when asked if he recalled telling Mr. Bentley on May 30, 1997 that Abbott was "widening the spread for providers," Mr. Walker testified that he did *not* make that remark to Mr. Bentley. (*See id.*) In short, there is no "new evidence" relating to Abbott "marketing the spread" for Acyclovir that has come to light since the United States served its original Complaint.

The greater issue, of course, is the Government's implication, in its brief, that the entire conversation between Messrs. Walker and Bentley was new to the DOJ. In reality, the DOJ was informed about the alleged May 30, 1997 conversation just *hours* after it occurred. At 2:14 p.m. on May 30, 1997, Ven-A-Care sent DOJ attorneys Mark Lavine and T. Reed Stephens a transmittal that, among other things, claimed:

> At approximately 9:30am today, Zachary Bentley spoke with Mr. Dennis M. Walker, Manager, National Accounts for Abbott Labs on the telephone. Mr. Walker informed Bentley of Abbott's price reduction for their Acyclovir stating that Abbott was "**widening the spread for providers**."

(*See* Ex. D at R2-040767; Ex. E at R2-040757) (emphasis in original). At a minimum, this shows that the DOJ was made aware of Abbott's alleged "marketing the spread" for Acyclovir on the *very day* that the event took place. More likely, this suggests that the DOJ and Ven-A-Care were working together to develop evidence that Abbott "marketed the spread" for Acyclovir.[3] In either event, no "new evidence" has come to light about this issue that would justify the Government's 13th-hour attempt to add these claims to the case.

B. There Are No Acyclovir Claims In Which The United States Can Intervene.

The Government does not dispute that its attempt to bring claims relating to Acyclovir is premised on 31 U.S.C. § 3730(b), which allows the Government to intervene in claims brought and maintained by relators. As Abbott's opening brief showed, after the Government made its initial decision *not* to intervene in the portion of the Relator's complaint directed to Acyclovir (and other drug) claims, the Relator chose to forego its right to pursue the declined claims and amended its complaint to drop these claims (including all claims relating to Acyclovir) altogether. (Dkt. No. 4470 at 7-8.) This amendment rendered the previously-alleged claims relating to Acyclovir a legal nullity. *See Kolling v. Am. Power Conversion Corp.*, 347 F.3d 11, 16 (1st Cir. 2003) (amended complaint "completely supersedes" prior complaint); 6 CHARLES ALLEN WRIGHT ET AL., FEDERAL PRACTICE & PROCEDURE § 1476 (2d ed. 1990) ("Once an amended pleading is interposed, the original pleading no longer performs any function in the case. . . .").

[3] The possibility that Bentley was acting on behalf of the DOJ or his own attorneys is ethically problematic since, at the time, Abbott was a party represented by counsel, and had already produced documents to the DOJ in response to Government subpoenas.

The Government does not deny this procedural history. Nor does the Government cite any law or otherwise oppose the well-established principle that an amended complaint supersedes prior complaints and that allegations not included in the amended complaint "f[a]ll by the wayside." *Carver v. Condie*, 169 F.3d 469, 472 (7th Cir. 1999). Accordingly, the Government cites no law to oppose Abbott's contention that there simply *are no* Acyclovir claims alleged by a private party (Ven-A-Care) in which the Government can intervene now.

The Government does argue that claims relating to Acyclovir must still exist—even though no one took any action to prosecute them for over a year after the Government's intervention—simply because the Government has not given its affirmative, written approval for Ven-A-Care to "dismiss" claims relating to Acyclovir in the *ten years* since Ven-A-Care brought those claims to the Government's attention. (Opp. at 18-19.) As an initial matter, the Government's proposal reflects very bad policy. The Court should reject the Government's attempts to turn 31 U.S.C. § 3730(b)(1) into a savings provision that would allow the Government to revive claims that have lain dormant for years, even decades. Perhaps more important, this broad assertion of Government authority is not supported anywhere in law—indeed, the Government has not cited a *single case* endorsing this aggressive Executive Branch reading of the FCA.

Nor does the Government address the authority that does exist, cited in Abbott's opening brief, that demonstrates the inapplicability of § 3730(b)(1) here. (Dkt. No. 4470 at 8-9 & n.8.) As both a matter of plain language and interpretive case law, amending a complaint to drop claims is simply not the "dismissal" of an "action." *See, e.g., Transwitch Corp. v. Galazar Networks, Inc.*, 377 F. Supp. 2d 284, 288 (D. Mass. 2005). Nor does § 3730(b)(1) apply to the post-intervention time frame. *United States ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d

715, 721-22 (9th Cir. 1994). And perhaps most important, contrary to the Government's protestation, its written decision *not* to intervene in the Acyclovir claims "may be taken as tantamount to the consent of the [U.S.] Attorney to dismiss the suit." *Minotti v. Lensink*, 895 F.2d 100, 104 (2d Cir. 1990) (noting also that "[o]nce the United States formally has declined to intervene in an action. . . little rationale remains for requiring consent of the Attorney General before an action may be dismissed") (internal quotation marks omitted). The Relator did not need written governmental consent to drop its Acyclovir claims here.

As a backstop, the Government also suggests (again without authority) that "cases analyzing intervention under Fed. R. Civ. P. 24 . . . have absolutely no relevance to intervention under the FCA." (Opp. at 18.) Again, the Government ignores the authority to the contrary—which, on this point, comes straight from the Supreme Court—clearly demonstrating that Rule 24 intervention case law *is* relevant to interpreting the FCA. *See Rockwell Int'l Corp. v. United States*, 127 S. Ct. 1397, 1411-12 (2007) (analyzing general intervention law to determine whether government, as intervening party, may have its claims survive dismissal of Relator's complaint); *see also United States ex rel. Precision Co. v. Koch Indus., Inc.*, 31 F.3d 1015, 1017 (10th Cir. 1994) (holding, in "analysis [of] the word 'intervene' contained in § 3730(b)(5)" that "the statute implies intervention of the types set forth in Rule 24(b)(2)").

Even more tellingly, the Government offers no alternative framework in which to understand § 3730's reference to "intervention" apart from its ordinary understanding as embodied in the federal rules, and in fact, the Government has expressly recognized this obvious connection in prior cases. *See United States ex rel. McGough v. Covington Techs. Co.*, 967 F.2d 1391, 1394 n.3 (9th Cir. 1992) ("The government contends that 31 U.S.C. § 3730(c)(3) of the [FCA] confers on it the unconditional right to intervene under Rule 24(a)(1)"); *United States ex*

rel. Stone v. Rockwell Int'l Corp., 950 F. Supp. 1046, 1047 (D. Colo. 1996) ("[T]he United States moved to intervene in this *qui tam* action pursuant to 31 U.S.C. § 3730(c)(3) and Rule 24(b) of the Federal Rules."). As Abbott showed, the law of intervention provides that a party who seeks to intervene in an existing suit must take that action as he finds it, and cannot "intervene" as to issues that are no longer being contested. (Dkt. No. 4470 at 7.)

In sum: So long as the government seeks to "intervene" in a § 3730(b) Relator-initiated *qui tam* (as opposed to its separate right to bring suit in its own right under § 3730(a)), its ability to intervene is tied to the contents of the Relator's complaint.[4] Because the Relator had no Acyclovir claims as of May 16, 2006 (when leave to adopt the Government's Complaint-in-Intervention was granted), the Government could not "intervene" in them. The Government's contrary position cannot be sustained.

Ven-A-Care, for its part, contends that it did not abandon the Acyclovir claims when it adopted the United States' Complaint in Intervention, but, rather, only sought to "augment" the allegations in its Fourth Amended Complaint with those made by the United States. (Relator Opp. at 4-8.) Ven-A-Care claims that the "United States' Action alleged the same fraudulent conduct alleged in all of the Relator's Complaints, and therefore no claims related to that fraudulent conduct were dismissed." (*Id.* at 5.) Ven-A-Care's argument is both wrong and disingenuous, as the record clearly shows otherwise:

- Ven-A-Care's "Motion for Leave to Amend Complaint By Adopting United States' Complaint in Intervention" did not seek permission to "augment" or "supplement" its

[4] Indeed, it is arguable that the United States could bring a stand-alone 31 U.S.C. § 3730(a) suit for Acyclovir claims; however, such a wholly independent suit would not benefit from relation back to the Relator's complaint. *See, e.g.*, *United States ex rel. Malloy v. Telephonics Corp.*, 68 F. App'x 270, 273 (3d Cir. 2003) ("Rule 15(c) does not permit a complaint filed in one civil action to relate back to a complaint filed in a separate civil action."); *Bailey v. N. Ind. Pub. Serv. Co.*, 910 F.2d 406, 413 (7th Cir. 1990) ("Rule 15(c), by its terms, only applies to amended pleadings in the same action as the original, timely pleading" and is "inapplicable to a "claim. . . in a second, separate complaint"). If a § 3730(a) action were brought today, most if not all of the Acyclovir claims would be untimely, likely explaining the Government's persistence in trying to re-raise the Acyclovir claims in a Relator-based proceeding where the Relator has rendered them defunct.

Fourth Amended Complaint—it unambiguously sought to "amend its complaint" against Abbott "by *adopting* the United States' Intervention Complaint *as Ven-A-Care's complaint* against Abbott." (Ex. K to the initial brief at 1) (emphasis added). That Complaint in Intervention provided a specific list of "[t]he drugs and corresponding NDCs at issue in this case"—a list that did not include Acyclovir. (Ex. J to the initial brief at 10-11.) Allegations that Abbott caused false claims related to Acyclovir were not raised by the Government's Complaint in Intervention, and Ven-A-Care bought into that complaint wholesale.[5]

- In responding to Abbott's discovery requests, Ven-A-Care has made it very clear that the only "specific drugs at issue in this litigation" were those "referred to in the United States' [original] Complaint." (Ex. N to initial brief at 1-2.) Thus, here it is clear that Ven-A-Care's adoption of the Government's original Complaint *was* designed to be a substitute for, and to supersede, Ven-A-Care's prior complaints. *See Zousmer v. Canadian Pac. Air Lines, Ltd.*, 307 F. Supp. 892, 896 (S.D.N.Y. 1969).

- Even the Government has rejected Ven-A-Care's contention that the Government's Complaint alleges the "same fraudulent conduct alleged in all of the Relator's Complaints." (Relator Opp. at 5.) To the contrary, in its briefing relating to the deliberative process privilege, the Government stated that its "complaint focuses on very specific pricing and marketing conduct related to drugs comprising 45 NDCs." (Dkt. No. 4076 at 12.) Ven-A-Care's under-seal complaints, in contrast, span hundreds of NDCs.

Thus, plaintiffs' deliberate choice to drop Acyclovir from this case provides another ground to bar them from raising that drug now.

C. Even If There Were Acyclovir Claims For The Government To Intervene In, The Government Has Not Shown "Good Cause" to Do So.

And there is more: Even if there were claims relating to Acyclovir for the Government to intervene in, and even if the Government could demonstrate justification for granting leave to amend at this date under the Federal Rules of Civil Procedure, the Government still could not add this drug now because it must (and has failed to) show "good cause" under 31 U.S.C. § 3730(c) for a late intervention on these claims. The Government's brief, in ignoring this requirement, tacitly admits that no good cause is present here.

[5] Indeed, the Government's notice of intervention specifically stated that it "decline[d] to intervene in that part of the action against Abbott as to *all other drugs* . . . identified in this action," including Acyclovir. (Ex. I to initial brief at 3) (emphasis added).

Under the FCA, once the government has initially declined to intervene in a claim, "the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause." 31 U.S.C. § 3730(c)(3). There is no dispute that the Government declined to intervene in the Acyclovir claims initially. (Dkt. No. 4470 at 4.) As noted in Abbott's opening brief, the rationale behind allowing late intervention is based upon the discovery of "new evidence" that heightens the "magnitude or complexity of the fraud." (S. Rep. 99-345, at 26 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5291; Dkt. No. 4470 at 12-13.) For the reasons discussed above, there is no basis whatsoever for the Government's claim that it has discovered "new evidence" concerning Acyclovir. Accordingly, there can be no "good cause" under § 3730(c)(3).

D. The Government May Not, In Any Event, Amend Its Complaint Because It Did Not Seek Leave to Do So, and Leave Should be Denied.

In addition, the generally-applicable standards of Rule 15(a) also defeat the Government's attempt to add Acyclovir. As Abbott's opening brief demonstrated, that rule required the Government to seek leave of Court before amending its complaint, yet it has failed to do so. This failure not only justifies dismissing the new Acyclovir claims; it requires dismissal of the amended complaint in its entirety. (Dkt. No. 4470 at 9-12.)

The Government's position is that, because Abbott had not served a responsive pleading to the original Complaint-in-Intervention, the Government was entitled to amend as of right under Rule 15(a), making leave unnecessary. (Opp. at 3-5.) Yet, that provision applies only to the first amendment – all others require leave of court. Fed. R. Civ. P. 15(a). As Abbott showed in its opening brief, a complaint-in-intervention is itself an amended complaint. (Dkt. No. 4470 at 10 & n.9.) Thus, the Government was required to seek leave before amending again.

Attempting to sidestep this rule, the Government argues that it *is* a wholly separate party from the Relator for purposes of Rule 15(a) amendment purposes, but *is not* a wholly separate party from the Relator for Rule 15(c) relation back purposes. (Opp. at 3-5.) The Court should reject the Government's unsupported attempt to have it both ways.

The Government does not and cannot dispute that its original complaint (filed March 17, 2006) was, in fact, an amendment to the Relator's previous complaints. There is no question that, after having ten years to consider the matter, the Government has been provided an opportunity to file at least *an* amended complaint. However, focusing on its right as a "separate litigating party," the Government contends that Rule 15(a) provides it an unequivocal right to amend its "own pleadings" at least once before a responsive pleading has been filed. (*Id.* at 4.)

This argument cannot be squared with the FCA, which clearly provides that the Government steps into the shoes of the Relator when it intervenes, and which contemplates such a direct link between the Relator and the United States that they are effectively a single party for purposes of the pleadings. (*See* Dkt. No. 4470 at 9-10.) Indeed, this Court has expressly recognized this "direct link," noting that when the government intervenes, "it has the statutory right to *amend* the complaint"—and that this amended complaint is the "pleading styled as [the] 'complaint-in-intervention.'" *In re Pharm. Indus. Average Wholesale Price Litig.*, __ F. Supp. 2d __, 2007 WL 2058731, at *5-6 (D. Mass. July 17, 2007) (emphasis added). This Court further noted that "nothing in the FCA requires a complaint-in-intervention" and the "United States could elect to intervene by simply using the relator's complaint." *Id.*

Given the statutory link between the Relator and Government for Rule 15(c) purposes, there is no logical or legal basis why this link would not apply to Rule 15(a) as well. (The

Government offers neither logic nor law to suggest otherwise.) As the Complaint-in-Intervention was itself an amended complaint, further amendments require leave of court.

Further, as Abbott set forth in its opening brief, even if such leave had been sought, it should never have been granted. At the time the Government filed its First Amended Complaint, the parties were already two-thirds through the fact discovery period in this case. The Government cannot dispute that the fact discovery undertaken in this case—including document requests, interrogatories, and depositions—has focused particular attention on the NDCs and J-Codes alleged in the Government's original Complaint. (Dkt. No. 4470 at 5.) Indeed, since the outset of discovery, both the Relator and the Government have sought to limit their discovery to the drugs named in the Government's original Complaint. The Relator—who under the Government's theory was to be prosecuting claims relating to Acyclovir—objected to Abbott's discovery requests "[t]o the extent that these questions and requests are not limited to the specific drugs which are issue in the latest active pleadings" and indicated its "responses will be limited to the specific drugs at issue in this litigation referred to in the United States' Complaint." (Ex. N to initial brief at 2.)[6] The Government should not be permitted to alter the playing field this late in the game; it should not now be permitted to amend its complaint to add drugs and theories about which it has known for 10 years or more.

II. EACH NDC OR J-CODE REPRESENTS A SEPARATE SET OF CLAIMS FOR RELATION BACK PURPOSES.

As to the four drugs in the First Amended Complaint that were already at issue in the Government's original Complaint-in-Intervention, the vast majority of claims should be dismissed as untimely. Under this Court's interpretation of the FCA, claims raised in the

[6] The Government's claim that Abbott may have to engage in discovery relating to Acyclovir in another case (Opp. at 7) misses the point. It does not change the fact that Abbott will have to, among other things, re-depose several Government witnesses and issue new document requests and interrogatories relating to Acyclovir.

Government's Complaint-in-Intervention may not relate back if they are "unrelated to those asserted in the original [Relator] complaint." *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 2058731, at *6. As Abbott's opening brief showed, each new NDC or J-Code must be considered a separate set of claims for relation back purposes. (Dkt. No. 4470 at 18-19.)

In response, the Government argues that allegations are the same conduct, transaction, or occurrence so long as they both allege that the "spread" has been marketed (Opp. at 15), and that alternatively, relation back should be gauged by the pleading of drugs, not drug codes (*id.* at 16-18). Both of these propositions are wrong.[7]

A. The Government's Allegation Of A Similar Theory Of Liability—"Marketing The Spread"—Is Insufficient To Allow Relation Back.

Abbott's opening brief demonstrated that mere allegation of a theory of liability does not render every set of facts that allegedly fit that theory the same "conduct, transaction, or occurrence." *See, e.g., O'Loughlin v. Nat'l R.R. Passenger Corp.*, 928 F.2d 24, 27 (1st Cir. 1991) (separate allegations of injury, on different days, due to "unsafe and inadequate working conditions" at the same workplace could not relate back); *United States ex rel. Health Outcomes Techs. v. Hallmark Health Sys.*, 409 F. Supp. 2d 43, 45, 53 (D. Mass. 2006) (allegation of miscoding specific procedure did not relate back to claims of miscoding same procedure in a different year); *see also United States ex rel. Colunga v. Hercules Inc.*, No. 89-CV-954, 1998 WL 310481, at *1-2 (D. Utah March 6, 1998) (false claims allegations related to "improper alodining" of Titan IV and other missile systems did not relate back to allegations of "improper alodining" of Pershing II missile systems, as "[d]ifferent rocket systems became the subject of the complaint").

[7] The Government's claim that Ven-A-Care's original 1995 complaint "described the drug pricing and spread marketing scheme perpetrated by Abbott that defrauded both the Medicare and Medicaid programs" (Opp. at 11) is incorrect. Ven-A-Care's original complaint did *not* contain allegations about Abbott "marketing the spread" for any of its drugs. (*See* Ex. C to initial brief.) As to Abbott at least, allegations of marketing the spread first appeared in Ven-A-Care's August 13, 1997 Second Amended Complaint.

Here, the Government's relation back argument rests on this same error. Allegations that Abbott reported certain prices for Product X, thereby causing specific false claims to be submitted as a result, is different conduct from Abbott's setting a different price for a different Product Y and allegedly causing an entirely different set of false claims to be submitted. Indeed, this Court has recognized that FCA liability in this case necessarily must proceed "not only company by company, but drug by drug, NDC by NDC, and even . . . year by year." (Ex. F at 22:16-21.) Furthermore, the Government's position has no end point. It would permit any of the numerous drug codes that have been alleged earlier in this case—and long since allowed to fall by the wayside—to be kept in reserve, ready to be asserted against Abbott with no timeliness penalty simply by the Government's pleading of the same general and broad-based allegations of fraud for the new drugs. Indeed, the Government's position would allow it to include scores of drug products that have never before even been alleged. This is insufficient for relation back. (*See* Dkt. No. 4470 at 19.)

B. Relation Back Must Be Assessed Drug Code By Drug Code, As These Are The Units By Which The Actual False Claims Alleged Would Have Been Presented.

The Government also argues that relation back should be judged by the first time a "drug" is named—such as "sterile water" or "dextrose"—instead of by J-Code or NDC. The Government's proposed definition, while convenient for its litigation position, is completely at odds with the reality of how Medicare and Medicaid pharmacy claims are actually paid, and has no logical basis given the purpose of the FCA. It should be rejected, and relation back should proceed drug code by drug code—NDC by NDC and J-Code by J-Code.

The First Circuit has made it clear that "[e]vidence of an actual false claim is 'the *sine qua non* of a False Claims Act violation,'" and the FCA is violated only where the government has been "presented. . . [with] a false or fraudulent claim." *United States ex rel. Karvelas v.*

Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004) (internal citations omitted). Further, as the Government is well aware, Medicare and Medicaid drug reimbursement requires the provider or pharmacy to specifically identify a J-Code or NDC in its claims submission, not just the drug name.[8] Those claims are then paid by virtue of the J-Code or NDC identified in the claims form. Thus, the Government's own allegations of "marketing the spread" and fraudulent pricing would require Abbott to provide prices and market spreads on an NDC by NDC and J-Code by J-Code basis, and the actual false claims which would have been submitted would be tied to those codes. Measuring relation back by reference to the first time a drug *code* is mentioned is thus the only way to define the specific transaction that led to the submission of specific false claims.

The Government's reliance on this Court's July 30, 2007 order in the New York Counties case to dispute this obvious conclusion is disingenuous. There, this Court permitted the plaintiff to add NDCs for old drugs, but not NDCs for new drugs, to its amended complaint. The Court's decision seemed to be based on its specific instruction that "no new drugs" be added to the amended complaint. (Ex. G at 9:20-10:4.) What that order did *not* do, however, is state that the new NDCs would relate back to the first complaint in which the generic drug name was first mentioned. (*See generally* Opp. Ex. 6.) In fact, this Court has expressly stated that it has made *no* decision on the "standard for evaluating whether new claims . . . are time-barred." *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 2058731, at *6 n.5. And, as Abbott has shown, that standard should allow relation back only to the first complaint in which a particular NDC or J-Code is alleged. (Dkt. No. 4470 at 18-20.)

[8] *See* Complaint ¶ 34 ("For the most part, in the Medicaid program, claims submitted by retail pharmacies are processed and tracked using the NDC of the drug."), 35 ("The Medicare program generally uses the Healthcare Common Procedural Coding System ('HCPCS') to reimburse for drugs. The HCPCS which [sic] utilizes 5-digit alphanumeric codes to identify and bill for medical products and supplies.").

Accordingly, if relation back is permitted at all (and it should not– *see* Dkt. No. 4470 at 14-18), it should be limited as set out in the chart attached as Ex. A to Abbott's opening brief:

- The 28 claims raised for the first time in ComplaintR3 (five of which were raised in ComplaintR1, but as set out above, that does not matter) were not alleged until August 12, 1997; because they may relate back only to that complaint, all claims accruing prior to August 12, 1991 are time-barred.[9]

- The 25 claims first raised in ComplaintR5 were not alleged until December 11, 2002; because they may relate back only to that complaint, and thus all claims prior to December 11, 1996 are time-barred.

- Finally, assuming that the four HCPCS codes not contained in any *qui tam* complaint are properly in this case (and they are not), they were first alleged in ComplaintG1, filed March 17, 2006; because they may relate back only to that complaint, all claims prior to March 17, 2000 are time-barred.

C. Even If The Court Allows Relation Back To Ven-A-Care's Later Complaints, No Claims Can Relate Back To Ven-A-Care's Original 1995 Complaint.

As explained in Abbott's opening brief, even under a relation back theory, the Government's claims cannot relate back to Ven-A-Care's original 1995 complaint because Ven-A-Care amended that complaint to drop Abbott. (Dkt. No. 4470 at 19-20.) *See, e.g., Jorge v. Rumsfeld*, 404 F.3d 556, 563 (1st Cir. 2005); *Harber Ins. Co. v. Essman*, 918 F.2d 734, 737 n.3 (8th Cir. 1990); *Dade County v. Rohr Indus., Inc.*, 826 F.2d 983, 989 (11th Cir. 1987). For this reason, any claims accruing prior to August 12, 1991, six years before the date that Ven-A-Care's Second Amended Complaint re-pled allegations against Abbott, are time-barred.

Citing 31 U.S.C. § 3730(b), the Government asserts that the unilateral dismissal of Abbott "did not break the relation back chain" to the original 1995 Ven-A-Care complaint because "the United States never gave its written consent to the [Ven-A-Care] March 28, 1997 dismissal pleading as required under the FCA." (Opp. at 11-12.) The Government, however, reads too much into § 3730(b). That provision does not speak to the relation back issue, and

[9] The United States has alleged that the Acyclovir claims did not accrue until April 22, 1997; thus, even if not otherwise dismissed, there are no Acyclovir claims before that date. (Dkt. No. 4281 at 27-29.)

there is no reason to believe it was intended to allow relation back to a complaint that the relator considered worthy of dismissal. If the Government had reason to believe, from its own investigation, that claims against Abbott were meritorious, it could have brought its own action under § 3730(a). Section 3730(b) was not designed to be placeholder, for relation back purposes, allowing the Government to relate back to allegations that the relator has dropped and the Government has not yet deemed worthy of pursuing. Before there can be relation back, there must be at least some party (either the relator or the Government itself) that has reason to pursue—and is pursuing—allegations against a particular defendant. In short, Rule 15(c) is designed to allow relation back of claims arising out of the same conduct, transaction, or occurrence of actually pleaded, well-founded allegations, not to provide a tolling provision for investigations that might ripen into well-founded allegations.

In any event, regardless of § 3730(b), the fact remains that, as to Abbott, there simply is no valid 1995 complaint to relate back to because Ven-A-Care's March 28, 1997 First Amended Complaint (Complaint R2) "completely supersede[d]" Ven-A-Care's prior complaint, meaning the 1995 pleading "no longer performs any function in the case." *Kolling*, 347 F.3d at 16; WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 1476. Again, if the Government had reason to pursue the allegations against Abbott, there was nothing stopping it from pursuing its own action against Abbott under § 3730(a). At the very least, the Government could have objected to Ven-A-Care's March 28, 1997 dismissal of Abbott. The Government did neither.

CONCLUSION

For the foregoing reasons, and those cited in the Memorandum in Support, Abbott's Motion to Dismiss or Partially Dismiss the United States' First Amended Complaint should be granted.

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Respectfully submitted,

/s/ R. Christopher Cook
James R. Daly
Tina M. Tabacchi
Brian J. Murray
JONES DAY
77 West Wacker Drive, Suite 3500
Chicago, Illinois 60601
Telephone: (312) 782-3939
Facsimile: (312) 782-8585

R. Christopher Cook
David S. Torborg
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
Telephone: (202) 879-3939
Facsimile: (202) 626-1700

Counsel for Defendant Abbott Laboratories, Inc.

CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES, INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS OR PARTIALLY DISMISS THE FIRST AMENDED COMPLAINT to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 17th day of September, 2007.

/s/ David S. Torborg
David S. Torborg